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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/872,250 06/01/01 GRUBB

G AM100058

EXAMINER

HM22/0824

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AMERICAN HOME PRODUCTS CORPORATION  
PATENT LAW DEPARTMENT - 2B  
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MADISON NJ 07940

HUT, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/24/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/872,250

Applicant(s)

GRUBB, GARY S.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nordette® monograph (Physicians' Desk Reference, 50<sup>th</sup> edition, 1996, page 2755-2758) and Alesse® monograph (electronic Physicians' Desk Reference, April, 1997) in view of Katzung (Basic & Clinical Pharmacology, 6<sup>th</sup> edition, 1995, page 620) and Endrikat et al. (Contraception, 1997;55(3): 131-137).

Nordette® monograph teaches that an oral contraceptive composition containing 0.15mg of levonorgestrel and 30µg of ethinylestradiol (See page 2755, col. 3, Description Section).

Alesse® monograph teaches that an oral contraceptive composition containing 0.1mg of levonorgestrel and 20µg of ethinylestradiol (See first page, Description Section).

The references do not expressly teach the two compositions can be used in an oral contraceptive starter kit. The references do not expressly teach the kit contains written instructions describing the order of use of the cycle packs. The references do not expressly teach the use of norethindrone, norethindrone acetate, gestodene, and norgestimate in an oral contraceptive composition and kits.

Katzung teaches that norethindrone, northindrone acetate, and norgestimate are useful in oral contraceptive composition (See particularly page 620, Table 39-3, col. 3).

Endrikat et al. teaches that an oral contraceptive composition containing 20 $\mu$ g of ethinylestradiol and 75 $\mu$ g of Gestodene (See abstract).

It would have been obvious to one skill in the art when the invention was made to incorporate both Nordette<sup>®</sup> and Alesse<sup>®</sup> together with a written description of how to take the oral conceptive into a kit for oral contraception.

It would have been obvious to one skill in the art when the invention was made to employ different progestins such as norethindrone, northindrone acetate, gestodene, and norgestimate into an oral contraceptive composition and kit.

One of ordinary skill in the art would have motivated to incorporate both Nordette and Alesse together with a written description of how to take the oral conceptive into a kit for oral contraception because combining two compositions which are known to be useful for oral contraception individually into a single kit useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the inclusion of a written instruction including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art.

One of ordinary skill in the art would have motivated to employ different progestins such as norethindrone, northindrone acetate, gestodene, and norgestimate into an oral contraceptive composition and kit because norethindrone, northindrone acetate, gestodene, and norgestimate are known to be useful in an oral contraceptive

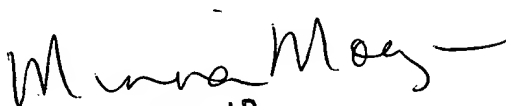
composition. The combining two agents which are known to be useful to oral contraception individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
August 20, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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